

Message Text

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UNCLAS NEW DELHI 3014

PASS DR. MORRIS T. JONES FOGARTY INTERNATIONAL
CENTER, NIH

E.O. 11652: N/A
TAGS: TPHY OSCI TBIO IN
SUBJECT: DHEW/PHS/NIH/SFCP AGREEMENT 01-024-N,
COLLABORATIVE NEUROLOGIC STUDIES (BACHHAWAT, MUKHERJEE, AUSTIN)

REF (A) STATE 239327 (B) NEWDELHI 13065 SEPT.16,1977

1. WE ARE CONCERNED ABOUT THE CONFLICTING SIGNALS WE
ARE RECEIVING FROM NIH ABOUT THE SUBJECT PROJECT. REFTEL
A SUGGESTED THAT NIH HAD SERIOUS DOUBTS THAT THE PROJECT
COULD BE REWRITTEN TO SATISFY NIH CRITERIA FOR FETAL
RESEARCH. SHORTLY AFTER RECEIVING REFTEL A, HOWEVER,
WE LEARNED FROM THE INVESTIGATORS THAT NIH
WAS ATTEMPTING TO WORK OUT SUITABLE PROCEDURES DIRECTLY
WITH THE INDIAN INSTITUTIONS CONCERNED. IN THESE CIR-
CUMSTANCES, WE DECIDED TO WAIT UNTIL THESE EFFORTS HAD
RUN THEIR COURSE BEFORE TAKING THE SUBJECT UP WITH THE
ICMR. IN RECENT WEEKS, WE RECEIVED A FORMAL QUERY FROM
ICMR ASKING THAT THE PROJECT BE CLEARED BY NIH AS SOON AS
POSSIBLE. AT THAT POINT WE INFORMALLY ADVISED DR. GOPALAN THAT THE PRO-

CEDURES FOR SAFEGUARDING THE SUBJECTS OF THE RESEARCH
WERE STILL THE SOURCE OF THE PROBLEM, BUT THAT WE HAD HEARD THAT NIH
WAS

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WORKING DIRECTLY WITH THE INVESTIGATORS IN AN EFFORT
TO RESOLVE IT. WE INDICATED THAT THIS WAS AT BEST A
LONG PROCESS, AND THAT IF TIME WAS A PROBLEM ICMR MIGHT
HAVE TO DRAW ITS OWN CONCLUSION ABOUT THE BEST
SOURCE OF FUNDING. DR. GOPALAN DID NOT ADDRESS THIS POINT.

2. WE HAVE NOW HEARD FROM ICMR THAT DR. JAMES AUSTIN

DESIGNATED US COLLABORATOR FOR THE SUBJECT PROJECT, HAS WRITTEN TO DR. GOPALAN THAT HE PLANS A TRIP TO INDIA APRIL 9-11 TO TRY TO BRING THE PROJECT TO FRUITION. IN ADVISING US OF THIS LETTER, ICMR QUESTIONED THE PURPOSE OF DR. AUSTIN'S TRAVEL, POINTING OUT THAT ALL THE NECESSARY GOI CLEARANCES HAVE ALREADY BEEN OBTAINED AND THAT THE ONLY CLEARANCE NOW NEEDED IS THAT OF THE US GOVERNMENT.

3. WE WOULD APPRECIATE WHATEVER INFORMATION NIH CAN GIVE US BOTH ON DR. AUSTIN'S PROPOSED TRAVEL AND WHAT HE HOPES TO DO IN INDIA AND ON THE CHANCES OF NIH CLEARANCE FOR THE PROJECT. REFTEL A SUGGESTED THAT THE PROJECT WAS MARGINAL FOR NIH. IN THE PAST FEW MONTHS, IT HAS BECOME APPARENT THAT OUR DELAY IN GIVING A DEFINITIVE RESPONSE IS COMPLICATING OUR RELATIONSHIP WITH ICMR. THE ICMR OFFICIALS DESPITE OUR BEST EFFORTS, DO NOT SEEM TO FULLY APPRECIATE THE SENSITIVITY OF RESEARCH ON FETUSES AND PREGNANT WOMEN FOR THE USG, AND HAVE CONSISTENTLY TAKEN THE POSITION THAT SINCE THE NIH WAS PREPARED TO FUND THE PROJECT AT ONE POINT, LATER DEVELOPMENTS IN THE RESEARCH FIELD SHOULD NOT INTERFERE WITH NIH APPROVAL AT THIS LATE STAGE. IF NIH'S REALISTIC APPRAISAL IS THAT THE PROJECT IS UNLIKELY TO MEET NIH RESEARCH CRITERIA, WITHIN A REASONABLE TIME, WE WOULD APPRECIATE KNOWING THIS SO THAT WE CAN GO OVER THE GROUND AGAIN -- MORE EXPLICITLY -- WITH ICMR, DIRECTLY ENCOURAGE THEM TO TAKE OVER THE PROJECT, AND REMOVE THIS IRRITANT FROM OUR DEA-
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LINGS WITH THIS KEY INSTITUTION.

4. IF DR. AUSTIN'S TRIP OUT HERE IS DESIGNED TO MAKE A FINAL ASSESSMENT OF THE POSSIBILITY OF WORKING OUT ADEQUATE SAFEGUARD PROCEDURES AND TO LEAD TO SOME KIND OF DETERMINATION AS TO WHETHER THERE IS ANY POINT IN PURSUING THE PROJECT WE WELCOME IT. UNLESS HE IS COMING OUT HERE WITH THE PURPOSE OF REACHING A FAIRLY CLEAR-CUT DECISION HOWEVER, WE ALSO QUESTION THE USEFULNESS OF HIS TRIP.

5. WE WOULD APPRECIATE ANY GUIDANCE NIH CAN PROVIDE. IF DR. AUSTIN IS COMING TO INDIA, IT WOULD BE VALUABLE TO GO OVER THE PROBLEM WITH DR. GOPALAN BEFORE HE ARRIVES, AND DR. GOPALAN HAS EXTENSIVE TRAVEL PLANS IN MARCH. SCIATT PLANS TO SEE DR. GOPALAN NEXT WEEK ON SEVERAL MATTERS, SO IT WOULD BE VERY HELPFUL TO HAVE GUIDANCE AS EARLY AS POSSIBLE.
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